

REMARKS

The Office Action dated May 13, 2008 has been received and noted. The following remarks are being submitted as a full and complete response thereto.

It is believed that a one month extension of time is required for responding to this Office Action. Accordingly, the extension of time is petitioned under 35 C.F.R. 1.136(a) and any fees required therefore are paid by credit card via electronic filing of this Response and Petition. It is further authorized to charge counsel's Deposit Account No. 01-2300, referencing **Attorney Docket No. 108140.00030**, for any additional fees necessary for entry of this Response.

In the Office Action, claims 1-6, 8-19, 21, 22, 29-38 and 40-46 have been rejected. Claims 20, 23-28 and 47 are withdrawn, claims 7 and 39 are cancelled and no claims are amended. Thus, claims 1-6, 8-38, and 40-47 are pending in this application. The Applicants respectfully request reconsideration and withdrawal of all the rejections.

Rejections Under 35 U.S.C. §112

Claims 29-31 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner asserts that the identity of the term "probe" in claim 29 is unclear and that the previous amendments to the claims do not overcome this rejection. The rejection is respectfully traversed and reconsideration is requested.

The Applicants respectfully submit that the term "probe" is described in the Specification as originally filed, at least at page 11, paragraph [00044]. Paragraph [00044] states that a probe may consist of a strip having several adsorbent wells and may having hydrophobic, strong anionic or weak cationic exchange surfaces under conditions which allow binding of

polypeptides. As stated in MPEP §608.01(o), the claims must be construed in light of the specification. Thus, the Applicants submit that the meaning of the term “probe” is apparent from the specification.

For at least the above reasons, the Applicants respectfully request withdrawal of the §112 rejection of claims 29-31.

Claims 1-6, 8-19, 21, 22, 29-38, and 40-46 are rejected under 35 U.S.C. §112, first paragraph. The Examiner contends that while the previous claim amendments do restrict the TSE to BSE or CJD, the claims retain the recitation: “comparing the test amount of the polypeptide in the sample to a reference amount of the polypeptide,” which is not linked to any specific amount, i.e., normal or abnormal. The Examiner maintains that the claims are not enabled because the comparison pertains to a reference amount, rather than the amount found in the normal samples. The rejections are respectfully traversed and reconsideration is requested.

Initially, Applicants submit that at least claims 2-3, 12-15, 32-33, 35-37, 40, and 43 are currently directed to embodiments in which the reference amount is specifically described as being present in the body fluid of a subject that either does, or, in some cases, does not have BSE or CJD. Applicants therefore respectfully submit that the rejection is not applicable to these claims.

Further, Applicants respectfully submit that it is well understood that for *in vitro* diagnostic assays, the signal in a test sample is compared against a signal from a normal or control reference sample. There is no requirement that the signal of the normal or control reference sample has to have an absolute value. The Applicants submit that one skilled in the art would understand that the size of the signal of the protein peaks is compared with diseased and

healthy samples to identify the discriminatory species. Thus, the Applicants submit that no absolute threshold is applied or required.


For at least the above reasons, the Applicants respectfully request withdrawal of the §112 rejection of claims 1-6, 8-19, 21, 22, 29-38, and 40-46.

CONCLUSION

Applicants respectfully submit that this application is in condition for allowance and such action is earnestly solicited. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below to schedule a personal or telephone interview to discuss any remaining issues.

Date: September 12, 2008

Respectfully submitted,



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